

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/443,853	11/19/99	PARIKH	1 121-184

NIXON & VANDERHYE P C
1100 NORTH GLEBE ROAD
8TH FLOOR
ARLINGTON VA 22201

HM22/1019

EXAMINER
KISHORE, G

ART UNIT	PAPER NUMBER
1615	18

DATE MAILED: 10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/443,863	11/19/99	PARIKH	I 121-184

NIXON & VANDERHYE P C
1100 NORTH GLEBE ROAD
8TH FLOOR
ARLINGTON VA 22201

HM12/1017

EXAMINER
KISHORE, G

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/17/01 ¹⁷

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/443,683

Applicant(s)

Parikh

Examiner

First Last

Art Unit

1234

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 14, 2001

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 14-49 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 14-49 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 15

20) ☐ Other:

Art Unit: :1615

DETAILED ACTION

The request for the extension of time, filing under 1.53 (d), 1.132 declaration and the amendment filed on 8-14-01, and the letter dated 8-14-01 are acknowledged.

Claims included in the prosecution are 14-49.

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants amend claim 1 to recite 'consisting essentially of'. Such a limitation requires that the specific components be recited and does not permit the addition of any compound or component which affects the novel characteristics of the composition. Instant dependent claims recite additional ingredients which appear to be essential components which affect the basic nature of the composition. Applicant has not addressed this issue and hence the rejection is maintained. Furthermore, it is essential that the bulking agents, releasing agents and surface modifiers be defined as specific compounds in the independent claims; for example, claim 16 recites inorganic additives and cellulose

Art Unit: :1615

based polymers as bulking or releasing agents whereas claims 30, 32 and 33 recites the inorganic material, colloidal clay and various celluloses as the surface modifiers.

The distinction between polysaccharides, and the natural polymers, synthetic polymer is unclear. Polysaccharides can be synthetic or natural. Similar is the case with tribasic calcium phosphate and a pH buffering salt in claim 20.

The distinction between a synthetic phospholipid and semisynthetic phospholipid is unclear. Irrespective of the starting substrate, if a derivative is synthesized, that said derivative will be a synthetic derivative.

It is unclear what applicant intends to convey by 'desalted' in claim 28.

Claim 29 recites trade names which is improper.

It is unclear how one can consider cholesterol as a surfactant as recited in claim 31. Similar is the case with various celluloses recited as surfactants in claim 32. Also not clear is what 'enteric resin' represents in claim 31.

The distinction between freeze-drying and lyophilization in claim 36 is unclear.

What is meant by 'antisolvent' in claim 38?

Art Unit: :1615

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 14-17, 19-34 and 35-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Green (5,976,577).

Green discloses rapidly dispersing oral dosage forms wherein the particles are coated with claimed components, The composition contains, other claimed components and the process of preparation involves the mixing of the components and lyophilizing the composition to form particles. (note the abstract, columns 5-8, Examples and claims).

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention

Art Unit: :1615

was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 1-17, 19-34 and 36-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green cited above.

As pointed out above, Green discloses instant process and the composition. What is not disclosed in Green is the range of claimed sizes. However, since Green's preparations are similar rapidly disintegrating particles coated with phospholipids and which dissolve in less than 10 seconds, it is within the skill of the art to vary the sizes taught by Green with the expectation of obtain the desired dissolution rates.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green cited above, further in view of Libby (4,432,975).

Green does not teach the inclusion of polyethylene glycol in the formulations. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to include polyethylene glycol in the quick disintegrating formulations of Green with the expectation of obtaining at least similar results since the reference of Libby shows the common practice in the art of inclusion of this compound in quick disintegrating formulations (note the abstract and col. 3).

8. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green cited above, further in view of Carli (5,164,380).

Art Unit: :1615

Green does not teach the inclusion of colloidal silica in the formulations. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to include colloidal silica in the quick disintegrating formulations of Green with the expectation of obtaining at least similar results since the reference of Carli shows the common practice in the art of inclusion of this compound in quick disintegrating formulations (note the abstract and Example 4).

The declaration submitted by applicant has been carefully considered, but has not been found to be persuasive for the reason that instant claims do not recite the critical process steps leading to the distinct particles formed as argued by applicant.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Art Unit: :1615

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

October 17, 2001